

THE CONCEPT OF EXCEPTIONALITY: A LEGAL FARCE?

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ABSTRACT

How do we decide which treatments should be offered by the National Health Service (NHS) when we cannot afford to fund them all? In the absence of a positive appraisal by the National Institute for Health and Clinical Excellence (NICE), which mandates the provision of a treatment by the NHS, Primary Care Trusts (PCTs) are free to decide whether to provide a particular drug to some, or all, of their population. However, as public bodies, it is a well-established principle of Administrative Law that PCTs are not at liberty to fetter the exercise of their own discretion. They must recognise the possibility that some patients will have exceptional circumstances, and as a consequence, any general policy prohibiting the funding of a drug cannot be absolute. In the absence of statutory guidance on what might constitute exceptional, clinicians are left guessing as to whether their patients might be eligible for funding on the grounds of exceptionality. Using the context of expensive cancer drugs, I will examine the concept of exceptionality from clinical, moral, and legal perspectives, focussing particularly on the role of social factors in determining exceptionality. I will review the cases where PCTs' decisions not to fund cancer drugs were subject to legal action and argue that the courts have provided little guidance on interpreting the term exceptional, and that the concept has a

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limited role to play in the allocation of scarce health resources at a local level.

Keywords: Allocation of resources for health care, Cancer drugs, Exceptional circumstances, Primary Care Trusts, Judicial review, Health and Social Care Bill 2010

I. INTRODUCTION

How should we decide which treatments are offered by the National Health Service (NHS), when we cannot afford to provide them all? Drugs that may extend the life of cancer patients have attracted much media attention. When requested by patients in the absence of a positive appraisal by the National Institute for Health and Clinical Excellence (NICE),¹ refusal of their provision has resulted in legal action against Primary Care Trusts (PCTs) who, at the time of writing, are the NHS authorities to whom difficult choices about such treatments fall. Looking forward, if the proposals outlined in the recent White Papers² and the Health and Social Care Bill³ are enshrined in law, the NHS will undergo the most radical reform instituted since its inception in 1948. PCTs may cease to exist and GP led Clinical Commissioning Groups will have to decide who receives treatments not affordable to all. However, it is important to look back and review the lessons we can learn from the past. Wherever the responsibility for commissioning health care services ultimately lands, the need to prioritise resources will remain.

Increasing the availability of cancer drugs is perceived as being politically popular.⁴ However, as the NHS operates within the constraints of a limited budget, such choices are inevitably accompanied by opportunity costs

¹ NICE has recommended provision by the NHS of 71% of the cancer drugs it has appraised. See National Institute for Health and Clinical Excellence, 'Nice and Cancer Drugs—the facts' <<http://www.nice.org.uk/newsroom/nicestatistics/niceandcancerdrugsthefacts.jsp>> accessed 17 January 2011.

² Department of Health, 'Equity and excellence: Liberating the NHS' (12 July 2010); Department of Health, 'Liberating the NHS: Commissioning for patients' (22 July 2010); Department of Health, 'Liberating the NHS: Local democratic legitimacy in health' (22 July 2010), Department of Health, 'The Cancer Drugs Fund: Guidance to support operation of the Cancer Drugs Fund in 2011–12' (23 March 2011); Department of Health, 'Healthy Lives, Healthy People: Our strategy for Public Health in England' (30 November 2010); Department of Health, 'Liberating the NHS: Legislative framework and the next steps' (15 December 2010).

³ Health and Social Care HC Bill 2010–11 [132].

⁴ As an example, David Cameron, during his 2010 election campaign, unexpectedly pledged that all end of life cancer treatments would be provided without regard to cost. See N Hawkes, 'The Political Power of Cancer' (2010) 340 BMJ 946–7.

elsewhere in the system.⁵ The establishment of NICE, in 1999, was seen as an attempt to depoliticise these decisions and put an end to unequal access to treatments in different localities. NICE has undertaken technology appraisals of new drugs and treatments, to establish clinical and cost effectiveness. Generally, drugs costing below a nominal threshold of £30,000 per quality adjusted life year (QALY) have been considered by NICE to be cost effective, although this threshold was raised in 2009 for treatments likely to extend the life of patients with less than two years to live, by more than three months.⁶ PCTs are under a legal obligation to make available all NICE approved treatments within three months.⁷ NICE has been subject to extensive criticism,⁸ but despite its weaknesses it is an improvement on the system it replaced, when well-educated and empowered patients had disproportionately greater access to many treatments, at the expense of the rest of the population.⁹ For the first time, it seemed, we had a health system which, true to its name, was providing a *national* health service. Every ticket in the postcode lottery was a winner. In light of this, it must have come as a surprise to Ann Marie Rogers, following her diagnosis of breast cancer, to learn that whilst Barbara Clark, living in Somerset, was able to receive trastuzumab (Herceptin) on the NHS, she, residing in nearby Wiltshire, could not.¹⁰ Ultimately, Ann Marie Rogers sought recourse to the courts to access this new monoclonal antibody, reported to halve the risk of recurrence of breast cancer.¹¹

⁵ In order to provide trastuzumab, one PCT had to cut their budget for learning disability services by £1 million/year. See *AC v Berkshire West Primary Care Trust* [2010] EWHC 1162 (Admin) 26 and A Barrett and others, 'How Much Will Herceptin Really Cost?' (2006) 333 BMJ 1118–20.

⁶ National Institute for Health and Clinical Excellence, 'Appraising life-extending, end of life treatments' (January 2009) <<http://www.nice.org.uk/media/88A/F2/SupplementaryadviceTACEoL.pdf>> accessed 30 January 2009.

⁷ Department of Health, 'Directions to Primary Care Trusts in England Concerning Arrangements for the Funding of Technology Appraisal Guidance from the National Institute for Clinical Excellence' (July 2003) <http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4075686.pdf> accessed 17 July 2008.

⁸ For a taste of the debate, see J Harris, 'Nice and Not So Nice' (2005) 31 Journal of Medical Ethics 685–8; J Harris, 'It's not NICE to Discriminate' (2005) 31 Journal of Medical Ethics 373–5; J Harris, 'NICE is Not Cost Effective' (2006) 32 Journal of Medical Ethics 378–80 and M Quigley, 'A NICE Fallacy' (2007) 33 Journal of Medical Ethics 465–6.

⁹ Department of Health and Social Security, 'Inequalities in Health: Report of a Working Group Chaired by Sir Douglas Black' (London 1980).

¹⁰ BBC News, 'Nurse wins breast cancer row' (3 October 2005) <http://news.bbc.co.uk/2/hi/uk_news/england/somerset/4304586.stm> accessed 21 July 2010.

¹¹ *R (Ann Marie Rogers) v Swindon NHS Primary Care Trust* [2006] EWHC 171 (Admin) and *R (Ann Marie Rogers) v Swindon Primary Care Trust and the Secretary of State* [2006] EWCA Civ 392.

How did this situation arise? At the time Ann Marie Rogers requested treatment with trastuzumab, it had not been appraised by NICE. Roche, its manufacturer, had not even applied for a product licence. PCTs can legitimately refuse to fund treatments not approved by NICE, save in exceptional circumstances.¹² Barbara Clark's PCT deemed her circumstances exceptional, whereas Ann Marie Rogers' PCT did not, resulting in her seeking judicial review of the PCT's decision. I will review the legal origins of the concept of 'exceptionality' and examine how it has been interpreted by the courts, in particular whether it is a term that should be applied solely to a patient's clinical condition, or whether social circumstances should also be considered. I will demonstrate that based on judicial review cases to date, it is not possible to establish criteria against which to determine if a patient is exceptional.

Individual funding requests for cancer drugs constitute the largest number of funding requests to PCTs on the basis of patients' exceptional circumstances.¹³ Cancer drugs were frequently the subject of such claims in part due to their relatively low cost effectiveness, resulting in them being less likely to gain NICE approval, and their high absolute cost, which makes them prohibitively expensive for PCTs to fund voluntarily, even for small cohorts. For many patients, they also represent the 'last chance' of active treatment at the end of life, making access a highly emotive issue. There is anecdotal evidence that funding patients on the basis of their exceptional circumstances is resulting in different survival outcomes from cancer within different PCTs.¹⁴ From an Oncologist's perspective, the concept of exceptionality appears to be a legal farce. Cancer patients should not be treated because they are exceptional, but because they are sick and have symptoms that need alleviating, for which an effective treatment is available. The concept of exceptionality therefore has limited application clinically, morally, and legally.

Acknowledging that every public authority must be careful not to fetter the exercise of its own discretion, I shall argue that exceptionality has been far too broadly and loosely defined. It is feasible that some drugs and treatments may have such low response rates, minimal benefits, and significant side effects that it would not be unreasonable to deny their provision without anticipating exceptional circumstances in which they might be funded.

¹² *R v North West Lancashire Health Authority, ex p A, D & G* [2001] 1 WLR 977, 991. PCTs can, of course, choose to commission drugs for their local population which are not approved by NICE.

¹³ National Prescribing Committee, 'A Comprehensive Survey of PCTs to Evaluate Local Decision Making Processes for Funding New Medicines' Slide 28 <http://www.npc.co.uk/policy/resources/npc_survey_report.pdf> accessed 6 October 2009.

¹⁴ Westminster Health Forum, 'The Cancer Reform Strategy - assessing the impact so far and next steps' (26 January 2010) 21.

II. WHERE DID THE LEGAL CONCEPT OF EXCEPTIONALITY ARISE FROM?

It is a well-established principle of administrative law that a public body is not entitled to fetter the exercise of its discretion.¹⁵ In the context of health care, this principle was made explicit in *R v North West Lancashire Health Authority, ex p A, D & G*,¹⁶ a case where three transsexuals were refused funding for gender reassignment treatment. Auld LJ acknowledged that within limited health budgets, health authorities have to establish priorities for funding. He went on to say

The precise allocation and weighting of priorities is clearly a matter of judgment for each authority, keeping well in mind its statutory obligations to meet the reasonable requirements of all those within its area for which it is responsible. It makes sense to have a policy for the purpose—indeed it may well be irrational not to have one.... It is proper for an authority to adopt a general policy for the exercise of such an administrative discretion, to allow for exceptions from it in '*exceptional circumstances*' and to leave those circumstances undefined...¹⁷

Auld LJ emphasised that such a policy must recognise the possibility of there being exceptional circumstances, such as overriding clinical need.¹⁸ This was interpreted in *Rogers v Swindon PCT and the Secretary of State* as meaning that

... withholding assistance save in exceptional circumstances... will be rational in the legal sense provided that it is possible to envisage, and the decision maker does envisage, what such exceptional circumstances might be.¹⁹

This interpretation by Clarke MR appears to raise the bar for allowing exceptions, from one where they could remain undefined, to one where it should be possible to envisage *what* such exceptional circumstances might be. This has resulted in a lack of clarity in the law. Exceptional cases often, by their very nature, cannot be identified in advance.²⁰ Although frequently cited in subsequent cases, in practice,

¹⁵ See *R v Port of London Authority, ex p Kynoch Ltd* [1919] 1 KB 176 and *R v Secretary of State for Home Department, ex p Venables* [1998] AC 407.

¹⁶ *R v North West Lancashire Health Authority, ex p A, D & G* (n 12) 989 and 994.

¹⁷ *R v North West Lancashire Health Authority, ex p A, D & G* (n 12) 991.

¹⁸ *Ibid.*

¹⁹ *R (Ann Marie Rogers) v Swindon Primary Care Trust and the Secretary of State* (n 11) para 62.

²⁰ This issue was highlighted by the defendant in *AC v Berkshire West Primary Care Trust* (n 5) para 31.

Clarke MR's comments have been taken to mean that it should be possible to envisage exceptional circumstances in general rather than specific terms.²¹ The courts have made it clear that it is not sufficient for PCTs to have a policy that theoretically allows for exceptions, when in reality a blanket ban is being enforced.²² In order to accommodate this requirement of allowing for exceptions to any general policy, PCTs have established Exceptional Case Panels to consider individual funding requests for treatments which are not funded for the general population.²³

Historically, there have been regional differences in the volume and outcome of individual requests for funding on the basis of exceptional circumstances, associated with a wide variation in the processes used to assess applications.²⁴ There were also marked variations in the time taken to process requests. The NHS Constitution, implemented in 2010, was a missed opportunity to standardise the individual funding request process. With respect to local decision making, it did little more than clearly communicate the already well-established legal right that such decisions should be made rationally after consideration of the evidence.²⁵ It was a survey of PCT processes by the National

²¹ *R (Jean Marie Murphy) v Salford Primary Care Trust* [2008] EWHC 1908 (Admin), para 6; *R (Colin Ross) v West Sussex Primary Care Trust* [2008] EWHC 2252 (Admin) para 35 and *AC v Berkshire West Primary Care Trust* (n 5) paras 32–33.

²² *R (Colin Ross) v West Sussex Primary Care Trust* (n 21) para 35. Professor Sir Bruce Keogh, NHS Director, has recently re-iterated this point in a letter for the attention of PCT Medical Directors. See 'Keogh warns NHS against 'blanket' treatment bans' Health Service Journal (10 October, 2011) <<http://www.hsj.co.uk/news/finance/exclusive-keogh-warns-nhs-against-blanket-treatment-ans/5036274.article>> accessed 25 October 2011.

²³ In different PCTs, these are known by a variety of names, including Individual Funding Request Panels, Clinical Priorities Committees, Commissioning Advisory Groups, and Effective Use of Resources Groups.

²⁴ For example, not all PCTs had written protocols for assessing funding requests, and where panels were used to consider requests, membership of the panel was not always made public. See Department of Health, 'Improving access to medicine for NHS patients'. A report for the Secretary of State for Health by Professor Mike Richards CBE (November 2008). I am currently undertaking an empirical study of the individual funding request decision making process, focussing on how PCTs interpret the term 'exceptional' and assess claims of exceptional circumstances. I intend to publish my results in due course.

²⁵ The Handbook to the NHS Constitution reads 'You have the right to expect local decisions on funding of other drugs and treatments to be rationally following a proper consideration of the evidence. If the local NHS decides not to fund a drug or treatment you and your doctor feel would be right for you, they will explain that decision to you'. Department of Health, 'The NHS Constitution' (March 2010) p. 6 <<http://www.nhs.uk/choiceintheNHS/Rightsandpledges/NHSConstitution/Documents/nhs-constitution-interactive-version-march-2010.pdf>> accessed 12 October 2010. The right of patients to receive an explanation of the outcome of decisions created a new obligation on PCTs. See n 37.

Prescribing Centre²⁶ which triggered guidance from the Department of Health, with the aim of standardising the assessment of these applications.²⁷ This guidance also emphasises the need to distinguish between a request for funding on the basis of exceptional circumstances and multiple requests from a heterogeneous population for a new drug, the latter being more appropriately managed through the submission of a business case for a service development by the treatment provider. No specific guidance is provided on the number of patients who could plausibly be regarded exceptional before a new policy should be formally considered. However, the NHS Confederation suggests that for highly unusual conditions, if more than one case per year is expected, a policy approach should be adopted.²⁸

III. A MATTER OF CLINICAL EXCEPTIONS OR RAISING EXPECTATIONS?

Many patients with cancer are exceptional, for a wide variety of reasons. Some are exceptional because of personal factors, such as the fortitude they demonstrate during treatment or the feats they accomplish during their illnesses.²⁹ Others are exceptional on clinical grounds, perhaps because of the rarity of their cancer, or the age at which they presented with a particular tumour type.³⁰ However, exceptionality is never a condition of treatment. In clinic, patients are not expected to show that their

²⁶ National Prescribing Committee (n 13) Slide 28.

²⁷ Department of Health, 'Defining Guiding Principles for Processes supporting Local Decision Making about Medicines' (January 2009) and National Prescribing Centre, 'Supporting rational local decision-making about medicines (and treatments) - A Handbook of Good Practice' (February 2009).

²⁸ The NHS Confederation, 'Priority Setting: Managing individual funding requests'(2008) p 10 <<http://www.nhsconfed.org/Publications/Documents/Priority%20setting%20managing%20individual%20funding%20requests.pdf>> accessed 4 October 2009.

²⁹ Few would deny, for example, that Jane Tomlinson, CBE, whose achievements after being diagnosed with incurable cancer included completing a marathon, a full ironman race, a 4200 mile bike ride across America and raising nearly £2 million, was an exceptional patient.

³⁰ One possible criterion for defining an exceptional disease course for cancer is presented in M Frenkel and others, 'Activism Among Exceptional Patients with Cancer' (2011) 19 (8) Supportive Care in Cancer 1125–32. For examples of such patients reported in the academic literature, see GB Challis and HJ Stam, 'The Spontaneous Regression of Cancer: A Review of Cases from 1900 to 1987' (1990) 29 Acta Oncologica 545–50; M Glasser, MZ Rosenberg and R Gaito, 'Widespread Adenocarcinoma of the Colon With Survival of 28 Years' (1979) 241 JAMA 2542–3 and W Snyder, RM Clark and JR Rubini, 'Long-term Survival of Mother and Son with Widespread Metastatic Adenocarcinoma of Colon' (1968) 21 Cancer 129–33.

need is greater than the next patient's, or justify their request for treatment on the basis of their domestic responsibilities, or social standing.³¹ Clinicians treat patients because they are ill, with the aim of returning them to full health, or improving their quality of life if this is not achievable.

The one respect in which a patient's exceptional features might be a consideration for the treating physician is if these features are *clinical* in nature, such as being particularly fit relative to others with the same stage of cancer, or having had a response of unusual magnitude, or duration, to a previous treatment. These might lead one to offer non-standard anti-cancer treatment, in the belief that they might gain more benefit from this than would normally be expected. Another small subset of patients whose exceptional features might result in them being offered non-standard treatment are those who suffer intolerable side effects from conventional treatment. Additionally, patients who are ineligible for clinical trials, or who are exceptional by virtue of having a rare cancer might, in the absence of an established treatment, be offered a drug not widely available on the NHS, were there strong hypothetical reasons to believe that this treatment might be of value.

In its current form, the exceptional funding route is used to access cancer drugs which are awaiting appraisal by NICE, or have been deemed not to be cost effective, when the treating Oncologist believes that the drug offers a realistic chance of benefitting the patient, usually when there are no alternative treatments available on the NHS. The trigger for requesting funding is therefore the patient's clinical need, rather than anything about their personal or social circumstances. It is an avenue of funding which clinicians are encouraged to explore by Department of Health guidance, before applying to the recently established Cancer Drug Fund³² or suggesting that

³¹ Declaration of Geneva, adopted by the 2nd General Assembly of the World Medical Association, Geneva, Switzerland, September 1948 and amended by the 22nd World Medical Assembly, Sydney, Australia, August 1968 and the 35th World Medical Assembly, Venice, Italy, October 1983 and the 46th WMA General Assembly, Stockholm, Sweden, September 1994 and editorially revised at the 170th Council Session, Divonne-les-Bains, France, May 2005 and the 173rd Council Session, Divonne-les-Bains, France, May 2006 <<http://www.wma.net/en/30publications/10policies/c8/index.html>> accessed 24 August 2010. The Declaration was intended to be a modernization of the Hippocratic Oath, and doctors graduating from around half of the UK's medical schools still recite a version of it, as a statement of their commitment to practicing in an ethical manner.

³² Department of Health, 'The Cancer Drugs Fund: Guidance to support operation of the Cancer Drugs Fund in 2011–12' (23 March 2011) pp 10–11 <http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_125445> accessed 10 October 2011.

the only option is private funding, through 'top up' fees, or otherwise.³³ It is therefore perhaps not surprising that some PCTs have been overwhelmed by exceptional funding requests, receiving up to 1,000/year.³⁴ Combined with a rejection rate of greater than 25%,³⁵ the end result, on a national level, is a large number of disappointed patients. Anger is a common reaction when patients feel they are being denied treatment.³⁶ Usually, the responsibility for communicating a PCT's rejection of funding is passed to the Oncologist providing care,³⁷ many of whom have consequently been reluctant to discuss unfunded drugs with patients.³⁸ Clinicians are being placed in the unenviable position of raising patient's hopes, only to shatter them. As I will demonstrate in a later section of this paper, the legal concept of exceptionality in the context of health is so elusive that Oncologists cannot use this as a basis on which to advise a patient as to whether or not it is likely to be worthwhile making an individual application for funding. A patient's 'exceptionality', as far as it is applicable to clinical management at all, is very limited. Clinical factors influence the choice of treatment offered, but the wide-ranging interpretation of the concept of exceptionality which has been applied by the courts bears little relevance to this.

IV. EXCEPTIONALITY: A JUST INEQUITY OR JUST INEQUITABLE?

The idea that PCT funding of cancer drugs, in some instances, hinges on whether or not a patient is exceptional does not sit comfortably with the

³³ Department of Health, 'Guidance on NHS patients who wish to pay for additional private care' (March 2009) p 8.

³⁴ National Prescribing Committee (n 13) Slide 5. Not all of these applications are for cancer drugs, but the survey revealed that the majority of requests for funding based on exceptional circumstances are for oncological treatments. Since the introduction of the Cancer Drugs Fund, the number of applications for cancer drugs is likely to have fallen significantly.

³⁵ Rarer Cancers Forum, 'Taking Exception: An audit of the policies and processes used by the PCTs to determine exceptional funding requests' (August 2008) p 11. <http://www.rarercancers.org.uk/news/current/new_rcf_report_reveals_striking_postcode_lottery_in_the_chances_of_having_an_exceptional_request_approved/rcf_taking_exception.pdf> accessed 20 August 2008.

³⁶ 'Bowel cancer patients missing out on essential treatment options' Beating Bowel Cancer Press Release, 25th March 2009 <<http://www.beatingbowelcancer.org/Resources/Downloads/PR%20090325.pdf>> accessed 21 July 2010.

³⁷ National Prescribing Committee (n 13) Slide 72.

³⁸ BMJ.com, A L Jones, 'JCCO survey on top up payments' 22 October 2008 <<http://www.bmjjournals.com/cgi/eletters/336/7659/1457#203489>> accessed 6 October 2009.

axiom that doctors should treat all patients with equal concern and respect. GMC guidance advises doctors that the:

... treatment you provide or arrange must be based on the assessment you and the patient make of their needs and priorities, and on your clinical judgement about the likely effectiveness of the treatment options You must treat your patients with respect whatever their life choices and beliefs. You must not unfairly discriminate against them by allowing your personal views to affect adversely your professional relationship with them or the treatment you provide or arrange.³⁹

That one individual with the same cancer should be treated differently from another, as occurred with Ann Rogers and Barbara Clark, when their respective PCTs passed differing judgments on whether their circumstances amounted to being exceptional, would appear to be a distinction not embraced by this code of conduct. Both women had breast cancer. Barbara Clark was considered exceptional by her PCT and received funding for trastuzumab, whereas Ann Rogers was not and had to seek judicial review of her PCT's decision in order to obtain funding for identical treatment.⁴⁰ If discriminating on the basis of age, colour, culture, ethnic or national origin, gender, lifestyle, marital or parental status, race, religion, beliefs, sexual orientation or social or economic status is not permitted, are there any non-clinical 'exceptional circumstances' that can morally be used to distinguish between patients when choosing who should have treatment funded? It is hard to think of any factors which would not fall under the umbrella of one of the GMC's categories. Non-urgent NHS treatment can legally be withheld from patients who are violent towards NHS staff, if their behaviour is not a product of their medical condition and they are deemed competent to take responsibility for their actions. In this instance, non-clinical factors are used to limit access to treatment, but this is driven by the need to ensure the safety of NHS staff, rather than the need to determine who should be prioritised for treatment when resources are limited.

³⁹ This includes personal views about a patient's age, colour, culture, disability, ethnic or national origin, gender, lifestyle, marital or parental status, race, religion or beliefs, sex, sexual orientation, or social or economic status. General Medical Council, 'Good Medical Practice- Guidance for Doctors' (March 2009) para 7. <http://www.gmc-uk.org/guidance/good_medical_practice/good_clinical_care_decisions_about_access.asp> accessed 15 July 2010.

⁴⁰ *R (Ann Marie Rogers) v Swindon NHS Primary Care Trust* (n 11); *R (Ann Marie Rogers) v Swindon Primary Care Trust and the Secretary of State* (n 11); BBC News, 'Nurse wins breast cancer row' (n 10).

In clinical practice, social circumstances are certainly a consideration in the management of medical conditions, and most clinicians aspire to providing holistic care, which inevitably encompasses social factors. In managing renal failure, for example, social considerations such as a patient's occupation may determine the type of dialysis offered. Someone with a manual job, in an unsanitary environment, might be offered haemodialysis over peritoneal dialysis. This decision would be based on the *clinical* risk of infection if peritoneal dialysis were undertaken in an unclean environment. NICE guidance for the management of pregnant women explicitly considers social factors such as homelessness, domestic abuse, and refugee status, but again this is because of the impact of these factors on *clinical* outcomes for this group.⁴¹ However, there are also examples where social factors are considered, where there is no direct clinical relevance. Religious beliefs can influence end of life care, particularly in intensive care units.⁴² Where this influences a decision to maintain active treatment, the cost implications can be significant.⁴³ An example of where occupation influences the urgency with which treatment is provided, again not based on clinical considerations, is the Department of Health mandate that armed forces veterans should be scheduled for treatment faster than others of similar clinical priority.⁴⁴ The practice is defended on the grounds that the armed forces put their lives and health at increased risk in the interests of others, although the same claim could be advanced for members of the fire service and other public sector employees. In the past, at least, social criteria were openly used to limit access to IVF, with provision on the NHS in some areas only being available to those who were married, or in a heterosexual relationship.⁴⁵ Here, it appears that resources were being

⁴¹ National Institute for Health and Clinical Excellence, 'Pregnancy and Complex Social Factors—Quick Reference Guide' (September 2010) <<http://guidance.nice.org.uk/CG110/QuickRefGuide/pdf/English>> accessed 4 October 2011.

⁴² CL Sprung and others, 'End-of-Life Practices in European Intensive Care Units' (2003) 290 (6) JAMA 790–7.

⁴³ For an example in the Canadian context, see *Golubchuk v The Salvation Army Grace General Hospital* 2008 MBQB 49, the case of an 85-year Orthodox Jew whose family's religious beliefs led them to take legal action to prevent his life support machine being turned off. Three physicians, who maintained the man had no chance of meaningful recovery, resigned over the case. The man remained on life support for over eight months and eventually died despite this.

⁴⁴ Department of Health, 'Continuing Care for Veterans' (2010) <http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_118493> accessed 11 September 2011.

⁴⁵ Ms Harriot was refused IVF on the grounds that she had a criminal record for prostitution offences, and had been rejected as a prospective adoptive or foster parent by social services. She challenged the decision, which was deemed lawful at judicial review. *R v Ethical Committee of St Mary's*

allocated according to what kind of families it was deemed desirable for public money to help create.⁴⁶

Beauchamp and Childress argue that social utility should be a criterion in priority setting, but only in emergency situations, such as pandemic flu. In this context, they advance that giving priority to health professionals and other essential workers is justified on the basis that it will increase the survival of the population as a whole. They advocate limiting judgments of social value to the specific attributes which will contribute to the protection of the community, rather than assessing general social worth.⁴⁷ Rescher goes further, claiming that where a social investment allows scarce medical technologies to be made available, the interests of wider society should help determine who should benefit. For this reason, he advocates assessing both a patient's past and likely future contribution to society.⁴⁸ Using social utility as a consideration in the allocation of health resources creates challenges of its own relating to the ways in which social utility is ranked, deciding whose idea of social value should be adopted, and whether those who could have conceivably contributed to their illness, through life style choices such as smoking and alcohol consumption, should be denied treatment, or given lower priority.⁴⁹ Discrimination could easily arise. If carers were favoured over non-carers, it is likely more women would receive preferential treatment. And if treatment necessary to enable someone to function at work was given priority, the employed would be favoured over the unemployed.

Prioritising treatment on the basis of a person's social function amounts to regarding them as a means to an end, rather than an end in themselves, contravening Kant's widely accepted categorical imperative.⁵⁰ Any such policy risks increasing inequity of access to

Hospital (Manchester) ex p Harriot [1988] 1 FLR 512. See also A Plomer, I Smith and N Martin-Clement, 'Rationing Policies on Access to in vitro Fertilisation in the National Health Service, UK' (1999) 7 Reproductive Health Matters 60–70.

⁴⁶ The ethics of this are beyond the scope of this paper. A detailed discussion can be found in MM Peterson, 'Assisted reproductive technologies and equity of access issues' (2005) 31 Journal of Medical Ethics 280–5.

⁴⁷ T Beauchamp and J Childress, *Principles of Biomedical Ethics* (4th edn, OUP, Oxford 1994) p 385.

⁴⁸ N Rescher, 'The Allocation of Exotic Medical Lifesaving Therapy' (1969) 79 Ethics 173–86.

⁴⁹ For a full discussion of the use of personal responsibility in the allocation of health resources see AM Buyx, 'Personal Responsibility for Health as a Rationing Criterion: Why We Don't Like It and Why Maybe We Should' (2008) 34 Journal of Medical Ethics 871–4. Draper and Sorrell also argue that patients have an ethical responsibility to promote their own health in H Draper and T Sorell, 'Patients' Responsibilities in Medical Ethics' (2002) 16 Bioethics 335–52.

⁵⁰ I Kant, *Foundations in the Metaphysics of Morals*, trans. Lewis Beck (Bobbs Merrill Company, Indianapolis 1959) at 47 [429].

healthcare and holds the potential to give rise to claims of discrimination based on human rights. Newdick argues that unless a person's circumstances are 'wholly exceptional', the practice should be avoided.⁵¹ On grounds of justice, it is time to move away from the idea that some patients are exceptional, whilst others are not, on the basis of their social circumstances. Irrespective of which theory of justice one subscribes to, fundamental to all is the principle of formal justice, attributed to Aristotle, that 'Equals should be treated equally, and unequals treated unequally'.⁵² This principle has been widely interpreted as meaning that with regard to the respects which are considered relevant to the issue in question, persons equal in those respects should be treated equally. It follows that despite the many differences between patients, no person should be treated unequally, unless the difference between them and others is relevant to the treatment in question. Social differences between patients are not morally relevant to the allocation of expensive cancer drugs and should not, therefore, be used in the determination of exceptionality.

Furthermore, the current policy of funding patients at a local level, on the basis of their 'exceptional circumstances', results in the unjust consequence that similar patients may be treated differently depending on the PCT area within which they reside. The case for giving PCTs greater control of the health budget was to enable the purchasing of health care to be more responsive to local needs.⁵³ The value of localism is in achieving more equal outcomes across heterogeneous regions. This is a valid goal where a community has a specific health problem relating to a particular population, or a local environment, but it makes a mockery of the concept of a 'national' health service when the management of some common cancers is determined on a local level. Postcode lotteries exist in other public services too, but given the extent to which health status impacts on life opportunities, inequality in health care provision is especially unjust. The current system also results in substantial inefficiencies if separate PCTs around the country have to review the evidence and cost effectiveness of new cancer drugs on an ad-hoc basis, as and when individual patients request funding.⁵⁴ Given the social

⁵¹ C Newdick, "Exceptional circumstances" - access to low priority treatments after the Herceptin case' (2006) (1) Clinical Ethics 205–8.

⁵² Aristotle, *Nichomachean Ethics* (2nd edn, Hackett, Indianapolis 1999) p 1131a10-b15.

⁵³ C White, 'Primary Care Trusts Need Local Flexibility to Deliver on Public Health' (2002) 324 BMJ 996.

⁵⁴ Some PCTs are now collaborating on a regional level to develop priority setting policies. The Priorities Support Unit, based in Oxford is an example of such an arrangement. <<http://www.sph.nhs.uk/priorities>> accessed 10 January 2011. It was acknowledged in *AC v Berkshire West Primary*

insurance nature of the NHS, patients have a legitimate expectation that even if the NHS cannot provide them with every available treatment, they will at least be treated in the same way as others using the service with the same need.⁵⁵

V. THE LEGAL CONCEPT OF EXCEPTIONALITY

A. *What Does It Mean to be Exceptional?*

The discretionary powers PCTs have with respect to determining exceptionality allow them significant flexibility and the ability to be responsive to the needs of individual patients. However, given how fundamental this concept of exceptional circumstances is in assessing individual funding requests, to leave these circumstances undefined presents a considerable challenge for PCT policy makers and results in their decisions being vulnerable to legal dispute.⁵⁶ Furthermore,

Care Trust (n 5) para 49 that PCTs could not be expected to conduct the same extent of research into new treatments as performed by NICE.

⁵⁵ The NHS Constitution goes somewhat to addressing this. See n 25. Harris argues that individuals' rights go beyond this, claiming that within a public health system, everyone should be entitled to an equal opportunity to benefit, irrespective of the chance of benefitting and irrespective of the quality and duration of that potential benefit. J Harris, 'Justice and Equal Opportunities in Health Care' (1999) 13 Bioethics 392–404.

⁵⁶ Unfortunately, space constraints prohibit a full examination of what the right and proper role of the courts in the context of health care priority setting should be. Daniels and Sabin have argued against the involvement of the judiciary in this setting, where the focus is on the individual patient, with little consideration given to the institutional context and interests of the wider community. They highlight the lack of technical expertise of legally trained judges, who may lack knowledge of health economics and clinical medicine. (See N Daniels and J Sabin, *Setting Limits Fairly - Learning to Share Resources for Health* (2nd edn, OUP, Oxford 2008) 59). This is in keeping with Lord Bingham's sentiment that the allocation of resources in health care was an issue 'not fitted' to the courts in *R v Cambridge Health Authority ex parte B* [1995] 1 WLR 898 at para 907. Contrary to this view, Stewart has advanced that administrative law has the potential to improve the process of decision making in resource allocation, increasing transparency and the public's awareness of why such decisions are needed. See C Stewart, 'Tragic Choices and the Role of Administrative Law' (2000) 321 BMJ 105–7. Similarly, Sheldrick argues that judicial review can do more than challenge decisions with which individuals disagree, 'leveraging access' to policy makers and 'opening up the system to a broader range of interests and voices'. See BM Sheldrick, 'Judicial Review and the Allocation of Health Care Resources in Canada and the United Kingdom' (2003) 5 Journal of Comparative Policy Analysis 149–66. James and Longley also believe that the courts have a role in explaining and justifying policy choices. R James and D Longley, 'Judicial Review and Tragic Choices: *ex parte B*' (1995) Public Law 367–73. Syrett reflects this sentiment, proposing that the courts have a role to play in enabling priority setting in healthcare to become a more deliberative process. K Syrett, 'Priority Setting and Public Law: Potential Realised or Unfulfilled?' (2006) 7 Med L Int 265–79. His

clinicians and patients are left uncertain as to patients' eligibility for this funding. In an attempt at clarity, and perhaps also to try and establish consistency in their decision making, some PCTs have formulated their own definitions of exceptionality. West Sussex PCT, for example, had advanced that exceptional means 'a person or thing or case to which the general rule is not applicable'.⁵⁷ Barking and Dagenham PCT had suggested that exceptional was 'not just "not the norm"'.⁵⁸ Both of these definitions were scrutinised during judicial review. As a consequence of the lack of an agreed legal definition of what constitutes exceptional, the interpretation of this term is often pivotal when decisions regarding funding in exceptional circumstances reach the courts. However, there are strict limits on the extent to which the court can intervene in such decisions.⁵⁹ The process of judicial review limits the courts to considering whether a PCT is guilty of procedural impropriety, has acted irrationally,⁶⁰ or beyond its powers. The court cannot substitute its judgement for that of the PCT, but is limited to quashing the decision or remitting it back for further consideration.

B. Do Previous Judicial Reviews Serve to Elucidate the Concept of Exceptionality?

1. An ordinary reading?

Given that the concept of exceptionality is such a source of contention, one might hope that when decisions relating to the funding of drugs in such circumstances are subject to judicial review some enlightenment as to how the term should be applied might be provided. Grenfell J, in *Ross v West Sussex PCT*, a case in which a man with multiple myeloma sought funding for lenalidomide, has been most explicit in this regard. Here, he advised that 'an ordinary reading' of the term exceptional should be upheld.⁶¹ Yet what constitutes an 'ordinary' reading? Did

book, K Syrett, *Law, Legitimacy and the Rationing of Health Care* (CUP, Cambridge 2007), provides a thorough exploration of the facilitative capabilities of public law in this context.

⁵⁷ *R (Colin Ross) v West Sussex Primary Care Trust* (n 21) para 28.

⁵⁸ *R (Victoria June Otley) v Barking and Dagenham NHS Primary Care Trust* [2007] EWHC 1927 (Admin) para 9.

⁵⁹ *R (Victoria June Otley) v Barking and Dagenham NHS Primary Care Trust* (n 58) paras 23–25.

⁶⁰ An irrational decision is one which is considered so demonstrably unreasonable, that no reasonable body could have reached it. This concept is commonly referred to as 'Wednesbury reasonableness', after the case from which it arose *Associated Provincial Picture Houses Ltd v Wednesbury Corp* [1948] 1 KB 223. Where breaches of the Human Rights Act 1998 are involved, the standard of proportionality, whereby any restriction on rights must be proportionate to the legitimate aim persuaded, can instead be applied. See *R (on the application of Daly) v Secretary of State for the Home Department* [2001] UKHL 26.

⁶¹ *R (Colin Ross) v West Sussex Primary Care Trust* (n 21) para 82.

Grenfell J mean for PCTs to open their Oxford dictionaries and apply the definition of exceptional as 'unusual, not typical' found within?⁶² If so, in what regard? With respect to clinical features, psychological status, family circumstances, socio or economic status? Many patients are unusual in one respect or another, so in itself, this definition is not discriminating enough. Rather than giving rise to a blanket ban, applying this definition could easily result in universal approval of individual funding requests, with all patients being considered exceptional and PCT coffers being quickly drained. PCTs would be as well to do without an exceptional funding policy and concede immediately to all patient requests for funding.

2. Consideration of social factors in determining exceptionality

Further examination of Grenfell J's comments reveals that making decisions based purely on social circumstances should be avoided where possible.⁶³ Remarks to this effect had also been made in *Otley v Barking and Dagenham PCT*,⁶⁴ the case of a fifty-seven-year-old woman with metastatic colon cancer, who having tolerated five cycles of privately funded bevacizumab, sought funding for further treatment from her PCT. This must be married with Clarke MR's assertion in *Rogers v Swindon PCT and the Secretary of State* that a PCT facing financial limitations could, reasonably, chose to fund cancer treatment for a woman caring for a disabled child, whilst not funding it for another with different personal circumstances.⁶⁵ This comment strongly suggests that in some instances, social circumstances can be a determining factor of exceptionality. However, Clarke MR also makes clear his view in this case that where limited resources are not a consideration, the PCT should concern themselves only with the clinical needs of the patient, and where these needs are equal, discrimination between patients on the basis of personal characteristics is not warranted.⁶⁶

In *Murphy v Salford PCT*, one of the non-clinical factors contributing to her exceptionality submitted by Jean Murphy, who sought funding for sunitinib to treat her renal cancer, was that she was the main carer for her husband.⁶⁷ In keeping with the example cited by Clarke MR, this was not dismissed by the judge as immaterial, but as a factor which should be considered in combination with all the other factors

⁶² *Concise Oxford English Dictionary* (11th edn, OUP, Oxford 2006).

⁶³ *R (Colin Ross) v West Sussex Primary Care Trust* (n 21) para 93.

⁶⁴ *R (Victoria June Otley) v Barking and Dagenham NHS Primary Care Trust* (n 58) para 9.

⁶⁵ *R (Ann Marie Rogers) v Swindon Primary Care Trust and the Secretary of State* (n 11) para 77.

⁶⁶ *R (Ann Marie Rogers) v Swindon Primary Care Trust and the Secretary of State* (n 11) para 79.

⁶⁷ *R (Jean Marie Murphy) v Salford Primary Care Trust* (n 21) para 17.

advanced.⁶⁸ Clarke MR suggests that a carer of a disabled child could be deemed exceptional, but provides no clue as to where the line should be drawn in considering social factors in the determination of exceptionality, or how different social factors should be weighed against each other.

It is the very recent case of *Condliff v North Staffs PCT*,⁶⁹ a case concerning bariatric surgery, which has finally brought clarity to this issue. Condliff was not obese enough to meet his PCT's criteria for funding of a gastric bypass. His doctor therefore applied for funding on the basis that he was exceptional. Various reasons to support this were advanced, including that he was housebound, could no longer attend church, or play the guitar.⁷⁰ When his application was declined, Condliff applied for judicial review. One of the grounds for judicial review was that North Staffs PCT had an established policy of excluding social factors from the assessment of exceptionality.⁷¹ Condliff claimed that this contravened his human rights under Article 8 of the European Convention on Human Rights. Judge Waksman deemed that social factors and Article 8 private factors are not synonymous, highlighting that whilst some private life factors may have clinical relevance, in which case they should be considered, not all social factors equate to private life matters.⁷² However, he accepted that because the PCT's policy of excluding social factors was capable of prohibiting considerations which might fall within the wide definition of private life under Article 8, it was imperative that he did review the lawfulness of the policy.⁷³

Judge Waksman subsequently dismissed Condliff's claim. He concluded that it would be difficult for PCTs to investigate the credibility of patients' social exceptionality claims, let alone objectively assess them, and that taking into account social factors would be unfair to others in the cohort against which the individual claiming exceptionality was compared, whose social circumstances were unknown.⁷⁴ In addition, he highlighted that unfair discrimination could arise if social factors were considered and reasoned that it was consistent for PCTs to follow the same broad approach as taken by the NHS in not considering social factors in treatment decisions, when they considered claims for funding on the basis of exceptionality.⁷⁵ However, it is noteworthy that during his judgement, Judge Waksman acknowledged that some

⁶⁸ Ibid, para 36.

⁶⁹ *R (Alexander Condliff) v. North Staffordshire Primary Care Trust* [2010] EWHC (Admin).

⁷⁰ Ibid, para 3.

⁷¹ Ibid, para 14.

⁷² Ibid, para 26.

⁷³ Ibid, para 30.

⁷⁴ Ibid, para 65.

⁷⁵ Ibid.

social factors might have direct clinical implications, and he distinguished these from 'non-clinical' social factors.⁷⁶

Condilff subsequently took his case to the Court of Appeal.⁷⁷ Again, it was concluded that the PCT's policy of excluding social factors did not bring Article 8 into play, and furthermore, it was deemed that even if it were applicable, the PCT's policy was within the margin of appreciation open to it, because it had reached a fair balance between meeting the needs of individual seeking treatment and the medical needs of the wider community.⁷⁸ The judge commented that Article 8 would not require the PCT to undertake a further balancing exercise for every individual funding request application.⁷⁹

3. Consideration of social factors awaits a European judgement

Condilff has now lodged an application at the European Court of Human Rights (ECtHR), challenging North Staffordshire PCT's refusal to approve the operation. Like the UK Courts, the European Court has consistently held that Article 8 has a limited role in decisions allocating health resources. The cases cited in *Condilff v North Staffs PCT* illustrate this. In *Sentges v Netherlands*,⁸⁰ which concerned a person with muscular dystrophy who sought a robotic arm, Article 8 was interpreted to protect the individual, creating negative obligations on public bodies and only exceptionally, positive obligations. In the latter instance, it was advised that a fair balance must be struck between individual and community interests, with a wide margin of appreciation in cases involving the allocation of resources. It was acknowledged that national authorities are in a better position to undertake this balancing act than the ECtHR. In *Pentiacova v Moldova*,⁸¹ where it was claimed that the state failed to provide adequate resources for dialysis, it was acknowledged that the boundaries between a State's positive and negative obligations do not lend themselves to precise definition. The need for a fair balance between competing individual and group interests, and the margin of appreciation enjoyed by the State were re-iterated. The ECtHR has sent a strong message that in the context of allocating healthcare resources, complying with Article 8 requires the balancing of conflicting interests, best undertaken by the State, and involves a margin of appreciation.

⁷⁶ Ibid, para 23. No examples were provided, but factors might include homelessness, domestic abuse, and refugee status. These factors are recognised by NICE as impacting on the clinical outcomes of pregnant women, see n 41.

⁷⁷ R (*Alexander Condilff*) v. North Staffordshire Primary Care Trust and the Secretary of State [2011] EWCA Civ 910.

⁷⁸ Ibid, para 52.

⁷⁹ Ibid, paras 31 and 54.

⁸⁰ *Sentges v Netherlands*, no 27677/02, 8 July 2003.

⁸¹ *Pentiacova v Moldova*, no 14462/03, 4 January 2005.

Other relevant cases include *Tysiak v Poland*⁸² and *X and Y v Netherlands*.⁸³ *Tysiak v Poland* concerned limited access to abortion, where the rights of eligible women were more apparent than real.⁸⁴ A positive obligation on States was found, to ensure that rights provided for, and within the remit of Article 8, could be properly adjudicated upon. *X and Y v Netherlands* did not concern access to medical care, but is relevant, because it identified a positive obligation on States to provide a framework for the enforcement of Article 8 rights.⁸⁵ These two cases were considered by the courts in *Condliff v North Staffs PCT*. In the first instance, the judge felt that it was nonsensical to consider a framework to either adjudicate or enforce Article 8 rights in this context, given that Article 8 rights are not generally engaged in resource allocation decisions in healthcare, and individual funding requests represent part of this process.⁸⁶ In the Court of Appeal, Toulson LJ said

In my judgment the Strasbourg jurisprudence not only does not support, but runs counter to, the proposition that it was unlawful for the PCT to adopt a policy that IFRs [individual funding requests] should be considered and determined exclusively by reference to clinical factors.⁸⁷

Condliff's hopes of success in the ECtHR look slim. However, a definitive answer from the European Court on the role of social factors in determining exceptionality maybe a long time coming. Before the judicial review of his case by the Appeal Court had been concluded, Mr Condliff re-submitted his individual funding request application with additional information, and his PCT have agreed that the new clinical information provided means he now meets the criteria for exceptionally. As a result, his case is unlikely to be expedited for consideration by the ECtHR. In the meanwhile, the English judiciary is clear; in the absence of direct clinical implications, social factors do not have to be considered in the assessment of exceptional circumstances.

4. Consideration of clinical factors in determining exceptionality

Consideration of clinical factors emerges from judicial reviews to date as less controversial, although there is little guidance as to how these

⁸² *Tysiak v Poland* (2007) 22 BHRC 155.

⁸³ *X and Y v Netherlands* (1986) 8 EHHR 235.

⁸⁴ *Tysiak v Poland* (n 82).

⁸⁵ *X and Y v Netherlands* (n 83).

⁸⁶ *R (Alexander Condliff) v North Staffordshire Primary Care Trust* (n 69) para 62.

⁸⁷ *R (Alexander Condliff) v North Staffordshire Primary Care Trust and the Secretary of State* (n 77) para 51.

should be prioritised. Reference is made to clinical need of an 'overriding nature',⁸⁸ but what constitutes an overriding clinical need? Auld LJ, in *NW Lancs v ex p A, D & G* elaborates on this, suggesting that authorities might give priority to life threatening and other 'grave' diseases.⁸⁹ He provides the examples of cancer, heart disease, and kidney failure as illnesses that one might expect to receive prioritisation over the treatment of transexualism.⁹⁰ That this intervention may reasonably be considered as low priority was re-iterated in the recent case of a male to female transsexual seeking breast augmentation on grounds of her exceptional circumstances, which it was advanced were physical in nature, due to poor breast growth in response to hormone treatment. Her claim for judicial review was dismissed, despite an appeal.⁹¹ However, there remains a dearth of guidance from the courts on how to prioritise between other illnesses, such as the examples of cancer, heart disease, and kidney failure provided by Auld LJ.

Despite Auld LJ's suggestion in *NW Lancs v ex p A, D & G* that life-threatening illnesses should be ordered a high priority for resource allocation, there has been no consensus over prognosis in subsequent judicial reviews. In *Rogers v Swindon PCT*,⁹² it was acknowledged that the PCT's Exceptional Circumstances Urgent Review panel had considered whether prognosis might be a factor in determining exceptionality and concluded that it could not. This was not disputed in the course of the appeal.⁹³ Duration of survival was also discussed in *Gordon v Bromley PCT*. Linda Gordon was a non-smoker, who developed lung cancer. She initially raised private funds to finance the drug erlotinib before applying, unsuccessfully, to her local PCT for continued funding. Although duration of survival was not considered to be applicable to the claimant, Ouseley J acknowledged that there may be instances where the need for short-term survival constitutes exceptional circumstances. The example, advanced by counsel for the defence, was when someone had to make arrangements for the care of children.⁹⁴ The issue of prognosis also arose in *Otley v Barking and Dagenham PCT*. Mitting J highlighted the possibility that treatment with bevacizumab, the drug at the centre of the judicial review, might shrink Victoria

⁸⁸ *R v North West Lancashire Health Authority, ex p A, D & G* (n 12) 990–991 and *R (Ann Marie Rogers) v Swindon Primary Care Trust and the Secretary of State* (n 11) para 62.

⁸⁹ *R v North West Lancashire Health Authority, ex p A, D & G* (n 12) 991.

⁹⁰ *R v North West Lancashire Health Authority, ex p A, D & G* (n 12) 990.

⁹¹ *R v Berkshire West Primary Care Trust* [2011] EWCA Civ 247.

⁹² *R (Ann Marie Rogers) v Swindon NHS Primary Care Trust* (n 11).

⁹³ *R (Ann Marie Rogers) v Swindon Primary Care Trust and the Secretary of State* (n 11) para 46.

⁹⁴ *R (Linda Gordon) v Bromley NHS Primary Care Trust* [2006] EWHC 2462 (Admin) para 41.

Otley's liver metastases sufficiently to enable a potentially curative resection.⁹⁵ He did not explicitly suggest that this factor should be determinative of exceptionality, but his repeated reference to the PCT's failure to evaluate the possibility that the treatment might have an impact on long-term survival suggests he thought that prognosis was relevant to the assessment of exceptionality.⁹⁶

5. Exceptional in comparison to whom?

A more detailed analysis of judicial review of PCT decision making in exceptional circumstances elicits several further principles with respect to determining exceptionality. One of the earliest to emerge was that the index case should be compared against the cohort of people eligible for treatment when assessing exceptionality.⁹⁷ This appeared to provide a clear benchmark against which comparisons of 'unusual' features could be determined, until the subsequent judgement in *Ross v West Sussex PCT*. The latter judicial review suggested that the index case cannot be deemed *unexceptional* simply because he is representative of a group of patients.⁹⁸ The standard of uniqueness Grenfell J perceived West Sussex PCT to have set was considered unreasonable.⁹⁹ Combining these two outcomes leads one to conclude that whilst the comparator is the cohort eligible for treatment, the index case does not have to be uniquely different to other members of that class to be exceptional. As a clinician, this leaves one perplexed. Exactly how different from his peers does a patient need to be for it to be worthwhile pursuing funding on the basis of exceptionality?

6. Does an increased likelihood of benefit from treatment make one exceptional?

Demonstrating features which suggest the index case is more likely to benefit from treatment than others does not invariably make the index case exceptional in the eyes of the judiciary.¹⁰⁰ This is a relevant clinical consideration when prescribing some cancer drugs, as several of the new monoclonal antibodies have been shown to be more effective in specific subgroups. Erlotinib, when used for non-small cell lung cancer, for example, has been shown in clinical trials to be more effective in those of Asian origin, lifelong non-smokers, and those with

⁹⁵ *R (Victoria June Otley) v Barking and Dagenham NHS Primary Care Trust* (n 58) paras 11–12.

⁹⁶ *R (Victoria June Otley) v Barking and Dagenham NHS Primary Care Trust* (n 58) paras 13, 16, 18, and 26.

⁹⁷ *R (Ann Marie Rogers) v Swindon Primary Care Trust and the Secretary of State* (n 11) para 67.

⁹⁸ *R (Colin Ross) v West Sussex Primary Care Trust* (n 21) para 78.

⁹⁹ *Ibid*, para 79.

¹⁰⁰ *R (Linda Gordon) v Bromley NHS Primary Care Trust* (n 94) para 39.

adenocarcinoma on histological examination.¹⁰¹ Linda Gordon possessed two out of three of these characteristics, associated with a statistically significant increase in the chance of a response, but Ouseley J was clear that possessing features which increased the likelihood of benefit did not inevitably make her exceptional.¹⁰² However, in *Otley v Barking and Dagenham PCT*, a case where the PCT was deemed not to have properly applied its own exceptionality criteria, the court gave significant weight to the fact that Victoria Otley was young and fit compared to other patients in her cohort, had suffered negative reactions to alternative treatment, and had appeared to benefit from the new drug without common side effects.¹⁰³ In her case, the increased likelihood of benefiting from the drug in question was considered a relevant factor. The inconsistency in the way this aspect was considered in these two cases is particularly incoherent from a medical perspective, as gaining more benefit from a treatment than might normally be expected is one of the few clinical justifications for treating a patient as an exceptional case.

7. Considering exceptionality in the round

One of the few very clear principles to emerge from judicial review of decision making by PCTs in exceptional circumstances is that all features that might contribute to the determination of exceptionality should be considered in their totality, rather than individually.¹⁰⁴ In *Murphy v Salford PCT*, Jean Murphy advanced seven reasons for her exceptionality, of both a clinical and social nature. These included that she had metastatic renal cancer, that she had a history of breast cancer, which made her ineligible for entry into a clinical trial through which she may have been able to obtain the treatment she sought, and a history of mental health problems which were exacerbated by the treatment initially used to treat her renal cancer. In addition, she suffered from other side effects which prevented administration of the full dose and was the main carer for her husband who suffered with multiple health problems.¹⁰⁵ The judicial review pivoted on the fact that the PCT had considered each of the factors individually and had found none of them on their own to be of enough significance for Ms Murphy's case to be classed as exceptional, but had not reviewed all

¹⁰¹ FA Shepherd and others and the National Cancer Institute of Canada Clinical Trials Group, 'Erlotinib in Previously Treated Non-Small-Cell Lung Cancer' (2005) 353 N Engl J Med 123–32.

¹⁰² *R (Linda Gordon) v Bromley NHS Primary Care Trust*, n, 94, para 39.

¹⁰³ *R (Victoria June Otley) v Barking and Dagenham NHS Primary Care Trust* (n 58) paras 20 and 26.

¹⁰⁴ *R (Jean Marie Murphy) v Salford Primary Care Trust* (n 21) para 31.

¹⁰⁵ *R (Jean Marie Murphy) v Salford Primary Care Trust* (n 21) para 33.

the factors ‘in the round’.¹⁰⁶ Burnett J was not satisfied that had all the issues been considered together, the decision would inevitably have been the same and he therefore ordered that the decision be retaken.¹⁰⁷ When the PCT re-evaluated Jean Murphy’s case in light of the judicial review, their decision that she was unexceptional remained unchanged.¹⁰⁸ There was no further legal challenge.

C. Is It Possible to Establish a Model of Exceptionality to Help to Advise Patients If They are Likely to be Considered Exceptional?

The criteria for determining exceptionality, to emerge from judicial review cases to date, can be summarised as follows:

- (i) An ordinary reading of the term ‘exceptional’ should be applied.¹⁰⁹
- (ii) Features of exceptionality should be reviewed ‘in the round’, rather than individually.¹¹⁰
- (iii) The index case should be compared against the cohort of people eligible for treatment,¹¹¹ but he cannot be deemed unexceptional because he is representative of a group of patients. He does not have to meet a standard of uniqueness.¹¹²
- (iv) In the absence of direct clinical implications, social factors do not have to be considered in the assessment of exceptional circumstances.¹¹³
- (v) Demonstrating an overriding clinical need for treatment presents a strong case for being considered exceptional.¹¹⁴
- (vi) Demonstrating features which suggest the index case is more likely to benefit from treatment than others can, but does not necessarily, make the index case exceptional.¹¹⁵

¹⁰⁶ Ibid.

¹⁰⁷ R (*Jean Marie Murphy*) v Salford Primary Care Trust (n 21) para 36.

¹⁰⁸ BBC News, ‘Cancer patient refused drug again’ (31 July 2008) <http://news.bbc.co.uk/2/hi/uk_news/england/manchester/7536138.stm> accessed 22 July 2010.

¹⁰⁹ R (*Colin Ross*) v West Sussex Primary Care Trust (n 21) para 82.

¹¹⁰ R (*Jean Marie Murphy*) v Salford Primary Care Trust (n 21) para 33.

¹¹¹ R (*Victoria June Otley*) v Barking and Dagenham NHS Primary Care Trust (n 58) para 78.

¹¹² R (*Colin Ross*) v West Sussex Primary Care Trust (n 21) para 79.

¹¹³ R (*Alexander Condliff*) v. North Staffordshire Primary Care Trust and the Secretary of State (n 77).

¹¹⁴ R v North West Lancashire Health Authority, ex p A, D & G (n 12) 990 and R (*Ann Marie Rogers*) v Swindon Primary Care Trust and the Secretary of State (n 11) para 62.

¹¹⁵ R (*Linda Gordon*) v Bromley NHS Primary Care Trust (n 94) para 39; R (*Victoria June Otley*) v Barking and Dagenham NHS Primary Care Trust (n 58) paras 20 and 26.

- (vii) The patient's prognosis need not be a consideration,¹¹⁶ but survival for a short period of time can make one exceptional, and the example provided is where care arrangements need to be made for a young child.¹¹⁷

However, these emerging principles are of limited value to PCTs, either in formulating policy for decision making in exceptional circumstances, or for determining whether an individual should be considered exceptional. If we take the five cancer patients who sought judicial review of the funding decisions made by their respective PCTs, Ann Rogers, Linda Gordon, Victoria Otley, Jean Murphy, and Colin Ross, and apply the criteria outlined above to them, using the information available to us in the court reports about their circumstances, the manifest lack of objectivity in the concepts that emerges, aside from the suggestion that social circumstances can be disregarded, means that each individual could be determined to be both exceptional and unexceptional, depending on how the criteria are interpreted. It is no wonder that PCTs find themselves in a conundrum when attempting to establish the existence, or otherwise, of exceptional circumstances and reach decisions that will withstand the scrutiny of the courts.¹¹⁸ All five of the cancer patients who resorted to judicial review were successful in getting their PCTs' decisions quashed.¹¹⁹ On a national level, around

¹¹⁶ *R (Ann Marie Rogers) v Swindon Primary Care Trust and the Secretary of State* (n 11) para 46.

¹¹⁷ *R (Linda Gordon) v Bromley NHS Primary Care Trust* (n 94) para 41.

¹¹⁸ Although operating against a background of different cultural values, Health Maintenance Organisations (HMOs) in Israel find themselves in a parallel situation. In Israel, the state covers the cost of a minimum package of health care, referred to as the basket of services. Patients wishing to access treatments not included in the basket can claim that their exceptional circumstances warrant the provision of additional services. If these claims are rejected by the HMOs, patients may seek judicial review. Similar challenges in defining exceptionality as described in the English context have been encountered. Attempts at creating criteria against which to consider exceptionality have been made and assessment is limited to objective medical criteria. However, disagreement between judges still exists and there is regional variation in the outcomes of similar cases. Gilbar and Bar-Mor argue that the use of the concept of exceptionality is appropriate despite its difficulties, but that more just outcomes could be achieved by including all life prolonging treatments in the basket of care, taking into consideration social and personal circumstances in the assessment of exceptionality, and limiting the discretion of HMOs. See R Gilbar and H Bar-Mor, 'Justice, Equality and Solidarity: The Limits of the Right to Health Care in Israel' (2008) 16 Med L Rev 225–60.

¹¹⁹ Subsequently, all received approval for funding of the requested drug by their PCT. Jean Murphy initially received two months funding for sunitinib from a private benefactor. She then reapplied to Salford PCT for funding, on the basis that she had responded unusually well to the drug. On this occasion, her IFR was approved. BBC News, 'Cancer patient wins drug battle'

half of patients who appeal their PCT's decision on exceptional funding are successful in reversing a negative outcome.¹²⁰ It is possible that PCTs concede to avoid costly court proceedings, which they are unlikely to win.¹²¹ The actual processes of applying for exceptional funding, appealing decisions, and seeking judicial review have become mechanisms of limiting access to drugs in themselves, with only the most empowered patients being able to pursue these avenues. Patients are often dependent on the Internet to obtain information about new drugs¹²² and many are not aware of the existence of the judicial review process, or the availability of pro bono legal assistance for those not eligible for legal aid.

1. An attempt at uniformity

The NHS Confederation suggests the following definition of exceptionality to aid PCTs in understanding the meaning of exceptionality within the individual funding request process:

The patient is significantly different to the general population of patients with the condition in question and the patient is likely to gain significantly more benefit from the intervention than might normally be expected for patients with that condition.¹²³

The first part of the definition is in keeping with *Rogers v Swindon PCT*¹²⁴ and *Ross v West Sussex PCT*,¹²⁵ in that the patient needs to be different from the cohort of patients with the condition, but not uniquely so. However, its usefulness is limited by the absence of guidance as to how the patient should be 'significantly different'. The latter half of the definition is consistent with *Otley v Barking and Dagenham PCT*,¹²⁶ which suggested that increased likelihood of benefitting from a drug was a relevant factor. This case was subsequent to

(22 October 2008) <<http://news.bbc.co.uk/1/hi/england/manchester/7685071.stm>> accessed 11 November 2011.

¹²⁰ National Prescribing Committee (n 13) Slide 61.

¹²¹ P Welsh, 'Sutent battle cost more than drug' *Manchester Evening News* (3 December 2008) <http://menmedia.co.uk/news/s/1083449_sutent_battle_cost_more_than_drug> accessed 22 July 2010

¹²² This is illustrated by *R (Ann Marie Rogers) v Swindon Primary Care Trust and the Secretary of State* (n 11) para 4 and *R (Victoria June Otley) v Barking and Dagenham NHS Primary Care Trust* (n 58) para 2. Both Rogers and Otley gained their knowledge about the new treatments they sought from the Internet.

¹²³ NHS Confederation, 'Priority Setting: managing individual funding requests', (2008) <<http://www.nhsconfed.org/publications/prioritysetting/pages/prioritysettingfunding.aspx>> accessed 7 July 2010.

¹²⁴ *R (Ann Marie Rogers) v Swindon NHS Primary Care Trust* (n 11) para 67.

¹²⁵ *R (Colin Ross) v West Sussex Primary Care Trust* (n 21) para 79.

¹²⁶ *R (Victoria June Otley) v Barking and Dagenham NHS Primary Care Trust* (n 58) paras 20 and 26.

Gordon v Bromley PCT when Ouseley J passed comment that possessing features which increased the likelihood of benefit did not inevitably make her exceptional.¹²⁷ Whether this definition can withstand legal scrutiny will not become apparent until a PCT which has adopted it is subject to judicial review.¹²⁸

VI. CAN THERE BE MORE THAN ONE LAWFUL ANSWER TO A POLICY QUESTION?

As judicial review is essentially an assessment of procedural, rather than substantive correctness, *prima facie* it appears that there could be more than one lawful answer to a policy question. This suggestion was advanced by Bean J in *Rogers v Swindon PCT*.¹²⁹ He was making reference to the fact that some PCTs had chosen to fund trastuzumab for the entire eligible group, whilst others had not. Although his ultimate judgement in this case was subsequently overturned by Clarke MR,¹³⁰ Bean J raises an interesting possibility. If there can be more than one lawful answer to a policy question, how would this apply to the funding of cancer drugs in exceptional circumstances? It would follow that a patient could legitimately be considered exceptional within one PCT, but not within another, as effectively happens at the moment with the so-called 'postcode lottery'. Why should the same person potentially be treated differently in two PCTs? One possibility is that X might appear exceptional in PCT A when compared with the cohort of patients with the same disease living in that region, but not when compared with the cohort of patients in PCT B. Thus, that X could be treated differently is based on the evidence that there are significant differences between two groups with the same disease but who live in different PCT regions. The existence of such factors is not implausible, and may relate, for example, to the genetics of the local population. These factors would seem most credible when the number of patients in each cohort is small; i.e. the disease in question is relatively rare. However, if the number of patients in each cohort is large, for example those with breast cancer, then it would seem unlikely that there would be significant differences between the populations with the

¹²⁷ *R (Linda Gordon) v Bromley NHS Primary Care Trust* (n 94) para 39.

¹²⁸ It is noteworthy that in *R (Alexander Condliff) v. North Staffordshire Primary Care Trust and the Secretary of State* (n 77) paras 19–25, the judge quoted extensively from the NHS Confederation document containing this definition. Although reference was not made to the definition itself, the document was clearly regarded as an authoritative source.

¹²⁹ *R (Ann Marie Rogers) v Swindon NHS Primary Care Trust* (n 11) para 68.

¹³⁰ *R (Ann Marie Rogers) v Swindon Primary Care Trust and the Secretary of State* (n 11).

disease in PCT A and B. Under these circumstances, if Patient X is considered exceptional against the comparator pool in PCT A, she should, logically, also be considered exceptional against the comparator pool in PCT B, which will consist of like patients to the comparator pool in PCT A. So, if Bean J is right, and the cohort against which exceptionality should be measured is those patients with the same condition, it follows that, at least with respect to determining exceptionality for the funding of cancer drugs, there should only be one policy answer to the policy question; a patient who is considered exceptional within one PCT should be considered exceptional within every PCT. This deduction presents a strong case for the determination of exceptionality on a national level, if the concept is to be used as the basis on which to allocate funding.

VII. MUST AN EXCEPTION BE ENVISAGED FOR EVERY INDIVIDUAL DRUG?

As discussed earlier in Section II, the principle that it must be possible to envisage circumstances in which a drug might be funded when declining applications on the basis of exceptional circumstances was established in *R v North West Lancashire Health Authority*¹³¹ and re-affirmed in *Rogers v Swindon PCT*.¹³² The first suggestion that this principle might be deviated from appeared in *Gordon v Bromley PCT*. In response to the question of whether Bromley PCT had imposed a blanket ban on the provision of erlotinib, Ouseley J suggested that:

The claimant might well go too far in saying that an exception must be capable of being envisaged for every drug in order for refusal in an individual case to be lawful.¹³³

He proceeded to give the example of a drug that ‘... may simply not have sufficient proven routine clinical benefit...’¹³⁴ However, in *Murphy v Salford PCT*, which was decided subsequent to *Gordon v Bromley PCT*, it was strongly re-affirmed that this original principle not only still held, but was not controversial.¹³⁵ It was also considered in *Ross v West Sussex PCT*¹³⁶ and *AC v Berkshire West PCT*.¹³⁷

Ouseley J’s remark that it might not be imperative to envisage an exception for every drug is worthy of exploration. Are there some drugs

¹³¹ *R v North West Lancashire Health Authority, ex p A, D & G* (n 12) 991.

¹³² *R (Ann Marie Rogers) v Swindon NHS Primary Care Trust* (n 11) para 62.

¹³³ *R (Linda Gordon) v Bromley NHS Primary Care Trust* (n 94) para 39.

¹³⁴ *Ibid*, para 39.

¹³⁵ *R (Jean Marie Murphy) v Salford Primary Care Trust* (n 21) para 6.

¹³⁶ *R (Colin Ross) v West Sussex Primary Care Trust* (n 21) para 35.

¹³⁷ *AC v Berkshire West Primary Care Trust* (n 5) paras 32–33.

and therapies for which there is so little evidence of benefit that it would be preposterous for a PCT to be expected to envisage exceptional circumstances when they might be funded?¹³⁸ If a PCT denied funding of Chinese herbal medicine, or Gerson Therapy,¹³⁹ would they be expected to envisage circumstances in which they would be provided? It may be that in the future, there will be licensed cancer drugs which are so expensive, and with such low response rates, which even when they do work provide very limited extension of life, accompanied by such significant side effects, that it would be reasonable to deny provision without being able to envisage exceptions where they would be funded. This is not to refute that the cancer patients whom they are designed to treat do not have an 'overriding clinical need', but unfortunately in many cases it is a need for which no effective magic bullet

¹³⁸ Assessing the clinical effectiveness of new treatments is a common challenge for exceptional case panels, as the treatments requested are often in early clinical use, or for rare conditions where little evidence exists. The traditional hierarchy of evidence places well conducted meta-analyses of randomised controlled trials (RCTs) at the top, followed by individual RCTs, observational studies (such as cohort and case control studies) and finally case studies and expert opinion. See T Greenhalgh, *How to Read a Paper—The Basis of Evidence Based Medicine* (4th edn, Blackwell Publishing, Oxford 2006) 16. In the absence of RCTs, PCTs must rely on forms of evidence lower down the hierarchy. Even when RCTs and meta-analyses exist, results may be conflicting. It is usual for Exceptional Case Panels to have at least one or two people specifically responsible for researching and presenting the evidence for requested treatments, often with a Public Health background. It is much less common for panels to include a hospital consultant, although supporting evidence is usually sought from the requesting physician. See National Prescribing Committee (n 13) Slide 11. In *R (Colin Ross) v West Sussex Primary Care Trust* (n 21) para 91 confusion over the outcome of some of the relevant trials was apparent. The limited information available in law reports may not reveal the true extent of this problem. Although there is no formal role for a medical expert 'witness' in the judicial review process, both parties can submit written evidence from a medical expert to support their position. Given the relatively low position of personal opinion in the evidence hierarchy, the weight which has been given to individual expert's views during judicial review is surprising. This is particularly apparent in *R (Victoria June Otley) v Barking and Dagenham NHS Primary Care Trust* (n 58) para 20 and *R (Colin Ross) v West Sussex Primary Care Trust* (n 21) paras 57, 71, and 72. In the latter case, the defendant challenged the claimant's medical specialist of straying into territory beyond his expertise, by commenting on the PCT's application of their exceptionality policy, but this objection was dismissed by the judge. It would appear that the limits of medical opinion in cases concerning exceptionality have yet to be defined.

¹³⁹ A controversial cancer treatment involving the consumption of fruit and vegetable juices, coffee enemas, and weekly injections of vitamin B12 and liver extract. The latter alone are reported to cost £20,000/year. 'Now Charles backs coffee cure for cancer' *The Observer* (27 June 2004) <<http://www.guardian.co.uk/society/2004/jun/27/themonarchy.medicineandhealth>> accessed 1 March 2010.

exists. If resource constraints were not an issue, it could be argued that little would be lost by trying drugs even with low effectiveness. However, in a social insurance health system, every treatment carries an opportunity cost. Providing an expensive cancer treatment with low effectiveness means that another patient, and possibly many other patients, will be deprived of treatments with better effectiveness. It is neither a rational or ethical use of limited resources to spend money on very high cost, low benefit, treatments. Whilst it would be an appropriate and logical action for a self-interested patient approaching the end of life, when funding is provided by a social insurance system, it makes no sense from a societal perspective.¹⁴⁰ That patients who apply for funding on the basis of their exceptional circumstances are identifiable makes these decisions harder, especially when individual's stories are sensationalised in the media, but statistical patients treated are of no less value than identified patients.¹⁴¹ A preference for identified lives is irrational and the heart wrenching tales in the court must be subject to dispassionate analysis, so that unknown patients without a voice do not suffer.

VIII. AN END TO LOCAL EXCEPTIONALISM?

Lord Darzi proposed to end the postcode lottery three years ago¹⁴² and Andrew Dillon, Chief Executive of NICE, has also called for consistency in PCT decision making.¹⁴³ In the absence of clear legal criteria on the determination of exceptionality, reaching decisions which are robust enough to withstand judicial review is challenging and PCTs are exposed to the risk of costly legal action. Furthermore, the money and time spent by PCTs on defensive legal action cannot be invested in improving clinical care.¹⁴⁴ Clinicians are left bewildered as to why some seemingly very similar patients are deemed exceptional, when others are not. The process of applying for funding on the basis of exceptional circumstances creates unrealistic expectations for patients, fuelled by

¹⁴⁰ DW Brock, 'Ethical and Value Issues in Insurance Coverage for Cancer Treatment' (2010) 15 *Oncologist* 36–42.

¹⁴¹ Ibid.

¹⁴² Department of Health, 'High Quality Care For All NHS Next Stage Review Final Report' (June 2008) p 44.

¹⁴³ E Webster, 'NHS boss slams the postcode lottery for life-saving drugs' *Bristol Evening Post* (18 August 2008) <<http://www.thisisbristol.co.uk/news/NHS-boss-slams-postcode-lottery-life-saving-treatments/article-273326-detail/article.html>> accessed 22 July 2010.

¹⁴⁴ This point was acknowledged by the judiciary in *R v Secretary of State for Social Services, ex p Walker* (1987) 3 BMLR 32, one of the early judicial review cases involving the allocation of resources for infant cardiac surgery.

media hype¹⁴⁵ and indirect marketing by pharmaceutical companies.¹⁴⁶ In addition, seeking recourse in the courts is not an option easily accessible to all, further increasing inequities between patients.¹⁴⁷

If there are inadequate resources to fund all effective cancer treatments, we should not hide behind the concept of exceptionality, but should have an open and honest debate as to how we reach a consensus on which drugs to fund, and how we are prepared to pay for those

¹⁴⁵ An example of the unbalanced coverage by national newspapers of new cancer drugs is provided by trastuzumab. Only 48% of news stories about trastuzumab referred to research undertaken on the drug, and only 6% mentioned the risk of cardiac side effects. See P Wilson and others, 'Deconstructing Media Coverage of Trastuzumab (Herceptin): An Analysis of National Newspaper Coverage' (2008) 101 J R Soc Med 125–32. The negative consequences of high profile media campaigns supporting individual patients seeking access to expensive cancer drugs is discussed further in G O'Reilly, 'Healthcare: Drug appraisal - A matter of life or death' PR Week UK (1 September 2008) <<http://www.prweek.com/uk/news/features/specialReports/931173/Healthcare-Drug-appraisal---matter-life.death/>> accessed 7 July 2010.

¹⁴⁶ Pharmaceutical companies are governed by strict guidelines with respect to direct marketing to patients, but human interest stories of individuals 'fighting' to obtain cancer drugs help raise public awareness and stimulate demand. Of 361 national news stories reviewed between 1998 and 2006 focusing on trastuzumab, 65% named breast cancer patients. See P Wilson and others (n 145). There is suggestion that the drug industry actively seeks out suitable patients to support through public relations companies. For example, after writing about her diagnosis of breast cancer, Professor Lisa Jardine was contacted by a public relations company working for Roche, and offered help in obtaining trastuzumab prior to its approval by NICE. See S Berg, 'Herceptin: Was patient power the key?' BBC News (9 June 2006) <<http://news.bbc.co.uk/1/hi/health/5063352.stm>> accessed 7 February 2010. Pharmaceutical companies also have a close relationship with patient advocacy groups, providing significant financial sponsorship. Given their common interest in increasing access to cancer drugs they are not uneasy bedfellows, but there is a risk that the association may result in a lack of objectivity on the part of patient groups. For a more detailed discussion, see K Jones, 'In Whose Interest? Relationships between Health Consumer Groups and the Pharmaceutical Industry in the UK' (2008) 30 Sociology of Health and Illness 929–43 and RE Ferner and SE McDowell, 'How NICE may be Outflanked' (2006) 332 BMJ 1268–71. The House of Commons Health Select Committee has recommended that steps should be taken to restrict the influence of drug companies on patient support groups, see Health of Commons Select Committee, 'The influence of the pharmaceutical industry: Fourth report of session' HC (2004–05).

¹⁴⁷ As Sheldrick highlights, multiple factors influence patients' access to the courts, including the existence, or not, of legal aid and the organisational capacity of interest groups. BM Sheldrick, 'Judicial Review and the Allocation of Health Care Resources in Canada and the United Kingdom' (2003) 5 Journal of Comparative Policy Analysis 149–66. For example, in her attempt to access trastuzumab from Bristol North NHS PCT, Elisabeth Cooke, a psychiatric nurse, was supported by the trade union Unison. 'Thompsons and trade union campaign for Herceptin' (12 June 2006) <www.thompsons.law.co.uk/ntext/thompsons-trade-union-campaign-herceptin.htm> accessed 7 January 2011.

treatments it is agreed should be provided. The Cancer Drugs Fund has widely increased access to oncological treatments, although evidence of regional variations in access is already beginning to emerge,¹⁴⁸ and there has been no evaluation of the opportunity cost to other health services of financing the Fund. With the introduction of value-based drug pricing, planned for January 2014,¹⁴⁹ and Clinical Commissioning Groups, there is a risk that access to cancer drugs could become an even bigger postcode lottery. Unlike PCTs, Clinical Commissioning Groups will not operate at arm's length from patients, and GPs may be more vulnerable not only to pressure from patients and their families, but also to the external influences which arise in funding requests on the basis of exceptionality, including those from the media, patient support groups, and the pharmaceutical industry.¹⁵⁰ The decision for the outcome of NICE technology appraisals to remain mandatory will help reduce this.¹⁵¹ When a drug is not nationally approved, there

¹⁴⁸ The Cancer Drug Fund is administered regionally, by Strategic Health Authorities (SHAs). The Rarer Cancer Forum reports that there are significant variations in application and approval rates between SHAs, and also in application rates by different providers. Rarer Cancers Forum, 'Funding Cancer Drugs—an evaluation of the impact of policies to increase access to cancer treatments' (June 2011) http://www.rarerancers.org/index.php?option=com_content&view=article&id=191:new-report-from-the-rarer-cancers-foundation-assesses-measures-to-improve-access-to-cancer-treatments&catid=43:england-news&Itemid=5 accessed 10 October 2011. Variations in access to cancer drugs between patients in England, Wales, and Scotland are even more marked, and this is directly attributed to the Cancer Drugs Fund. See Rarer Cancers Forum, 'Nations divided? An assessment of variations in access to cancer treatments for patients in England, Scotland and Wales' (August 2011) <http://www.rarerancers.org/index.php?option=com_content&view=section&layout=blog&id=5&Itemid=5> accessed 10 October 2011.

¹⁴⁹ Department of Health, 'A new value-based approach to the pricing of branded medicines - Government response to consultation' (18 July 2011) <http://www.dh.gov.uk/en/Consultations/Responsestoconsultations/DH_128226> accessed 10 October 2011.

¹⁵⁰ In a survey of PCT decision making in 'exceptional circumstances', ten PCTs admitted that local publicity and media influenced their decision making. 'Cancer patients facing exceptional difficulties to get funding for cancer drugs' Macmillan Press release (29 October 2008) <www.macmillan.org.uk/Aboutus/News/Latest_News/Cancer_patients_facing_exceptional-difficulties_to_get_funding_for_drugs.aspx> accessed 22 March 2011.

¹⁵¹ This decision to change the status of outcomes of NICE technology appraisals from mandatory to advisory was reversed during the Government's 'listening exercise' on the Health and Social Care Bill, when many GPs said they were not happy to effectively have the power to ration treatments. Removing NICE's mandatory powers would have moved the NHS from a position where local funding of the relatively few cancer drugs not approved by NICE was at the discretion of PCTs, to a position where the funding of all cancer drugs was at the discretion of Clinical Commissioning Groups. See A Gulland, ' NICE Confirms Its Role in New NHS after Government

will, on occasion be reason to treat one cancer patient differently from others with the same condition, on clinical grounds. For example, if there is reason to believe, they may benefit more from a treatment than usually expected, or if they suffer intolerable side effects from standard treatment. From a medical perspective, these patients could be considered exceptional. The restructuring of the NHS presents a perfect opportunity to start assessing these patients on a national, or at least supra-regional basis, to enable standardisation of the concept of exceptionality and consistency in the determination of exceptionality.¹⁵² This would be more just, ensuring that like patients are treated in the same manner, irrespective of their place of residence. A nationally ring fenced pot of money to fund those patients deemed to be exceptional would also prevent destabilisation of the budgets of the proposed new Clinical Commissioning Groups from the need to find funds to finance expensive treatments at short notice.

The misconception that all new cancer treatments emerging onto the market are wonder drugs must be challenged. This myth serves only to provide false hope and defer conversations about the end of life, a topic which both the healthcare profession and wider society need to learn to address more comfortably. This is not to say that the pharmaceutical industry should not be rewarded fairly for innovation. Drug research and development is expensive, but pharmaceutical companies spend twice as much on marketing as research.¹⁵³ Patient access schemes¹⁵⁴ and regulation of drug pricing may go some way towards making new cancer drugs affordable, but with the pace of development of medical

U Turn' 2011 (343) BMJ d4525 and Department of Health, 'Government changes in response to the NHS Future Forum' (June 2011) <http://www.dh.gov.uk/en/MediaCentre/Pressreleases/DH_127577> accessed 9 October 2011.

¹⁵² Consistency of decisions could be improved, if, for example, the individual funding decision process were to be run by clusters of Clinical Commissioning Groups, covering larger populations. In Wales, it has already been suggested that the appeals process for exceptional funding requests should move to a single national system. M Aylward, 'Health Commission Wales: A Review' (June 2008) <<http://www.wales.nhs.uk/sites3/Documents/568/Health%20Commission%20Wales%20A%20Review%20%28Eng%20Report%29.pdf>> accessed 10 January 2011.

¹⁵³ MA Gagnon and J Lexchin, 'The Cost of Pushing Pills: A New Estimate of Pharmaceutical Promotion Expenditures in the United States' (2008) 5 PLoS Med e1.

¹⁵⁴ Patient access schemes involve either the supply of a limited amount of free drugs, or drug rebates. Whilst having the potential to save the NHS money, such schemes have been criticised because of their high administration costs and the failure of the NHS to reclaim all monies due. For sunitinib alone, a drug used to treat kidney cancer, it is alleged the NHS has failed to reclaim nearly £4 million. For more detail see S Williamson and T Thomson, 'A Report Into the Uptake of Patient Access Schemes in the NHS' (2010) 2 Clinical Pharmacist 268–70.

technologies it is inconceivable that we will ever be able to afford every available treatment. Even if the health budget were to be increased, we would still need a fair and just way of deciding which treatments should be financed. Funding patients on the basis of exceptionality, determined locally, is not the answer.